

K161016 Z-Clamp ISP SystemOct 19, 2016
191 days to decisionK161016 · Product code: **PEK** · Orthopedic
Source: <https://www.510kdatabase.net/k161016/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Apr 11, 2016
Decision date	Oct 19, 2016
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zavation, LLC
Location	Brandon, MS, US
Contact	James M Philips
510(k) history	15 submissions · 15 cleared · 2011-2017

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